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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0080]

Draft "Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires" dated April 2002. The draft document, when finalized, is intended to provide guidance to blood and plasma collection centers on the recommendations of FDA for implementing self-administered donor questionnaires at the predonation donor screening interview. The draft guidance document also describes the information to be included in a biologics license application supplement or annual report for the implemented changes.

DATES: Submit written or electronic comments on the draft guidance document to ensure their adequate consideration in preparation of the final document by [insert date 60 days after date of publication in the FEDERAL REGISTER]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the

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draft guidance document to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT:

Michael D. Anderson,
Center for Biologics Evaluation and Research (HFM-17),
Food and Drug Administration,
1401 Rockville Pike,
Rockville, MD 20852-1448,
301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled "Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires" dated April 2002. The draft guidance document, when finalized, is intended to provide recommendations to the blood and plasma collection centers on the changes from the current predonation donor screening interview procedure to a self-administered format. The draft guidance document also describes the information to be included in a biologics license application supplement or annual report for the implemented changes. The draft guidance document does not address the informed consent process or specific screening questions, a specific questionnaire, or how to submit changes to the questions on a currently approved questionnaire.

The draft guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance document represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

The draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance document and on the collection of information. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by [insert date 60 days after date of publication in the FEDERAL REGISTER]. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cber/guidelines.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: 3/12/02.
March 12, 2002.

Margaret M. Dotzel,
Associate Commissioner for Policy.

~~[FR Doc. 02-????? Filed: ??-??-02; 8:45 am]~~

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Dawn P. Hawkins